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June 10, 2005

BY HAND DELIVERY

Marlene H. Dortch, Secretary
Federal Communications Commission
445 12th Street, S.W.
Washington, D.C. 20554

Re: Notification of Transfer of Subscribers from Akron Canton Communications, Inc. to First Communications LLC – **Docket No. 00-257**

Dear Secretary Dortch:

Pursuant to Section 64.1120 of the Commission's rules, 47 C.F.R. § 64.1120, First Communications LLC. ("First Communications"), by its attorneys, respectfully notifies the Commission that, in furtherance of a transaction whereby First Communications will acquire substantially all of the assets of Akron Canton Communications, Inc. ("Akron Canton"), First Communications intends to acquire all of the customers of Akron Canton. First Communications is complying with the Commission's rules and procedures governing compliance with section 258 of the Communications Act of 1934, as amended, including the provision of advanced written notice to all affected customers.

In conformity with Commission rules, First Communications provides the following information:

Parties to the Transaction: The parties involved in the transaction are Akron Canton Communications, Inc. ("Akron Canton"), and First Communications LLC ("First Communications"). First Communications entered into the Agreement with Akron Canton to acquire substantially all of the assets of Akron Canton, including its customers.

Types of Telecommunications Services Provided to the Affected Subscribers: Akron Canton provides local and long distance resale telecommunications services to both residential and business customers. First Communications will provide the same services to these subscribers. Akron Canton customers will not experience a diminishment in services as a result of this transaction.

residential and business customers. First Communications will provide the same services to these subscribers. Akron Canton customers will not experience a diminishment in services as a result of this transaction.

Date of Transfer of the Subscribers to Acquiring Carrier: The acquisition of subscribers from Akron Canton to First Communications, relevant to this Notice, is expected to occur on or after July 15, 2005. First Communications will provide the attached notice to all Akron Canton customers at least 30 days prior to the proposed transfer.

Attached to this letter are (a) First Communications' certification of compliance with the requirements of the Commission governing transfers of subscribers, and (b) copies of the notices sent to the affected business and residential subscribers, as required under the rules.

Please contact the undersigned if you have any questions concerning this notification.

Respectfully submitted,

Steven A. Augustino
Karly E. Baraga
KELLEY DRYE & WARREN LLP
1200 19th Street, N.W., Suite 500
Washington, D.C. 20036
(202) 955-9600

Counsel for First Communications LLC

Attachments

ATTACHMENT A

CERTIFICATION OF COMPLIANCE

CERTIFICATION OF FIRST COMMUNICATIONS LLC.

The undersigned hereby certifies as follows:

1. I have read the foregoing document and hereby verify that the statements therein are true, complete and correct to the best of my knowledge.

2. In accordance with Section 64.1120(e) of the Commission's rules, 47 C.F.R. §64.1120, First Communications LLC. will comply with the required FCC procedures for the acquisition of all of the customers of Akron Canton Communications, Inc. including the provision of advanced written notice to all affected subscribers.

FIRST COMMUNICATIONS LLC.

By:_____

Name: Joseph R. Morris

Title: VP of Corporate Operations

Date: 6-9-05

Sworn and subscribed to before me this
9th day of June, 2005.

_____
Notary Public

My Commission expires:_____

ERIC S. LOCKSHIN, Notary Public
Residence - Summit County
State Wide Jurisdiction, Ohio
My Commission Expires Feb. 25, 2007

DC01/BARAK/234063.1

ATTACHMENT B

CUSTOMER NOTICE

ACCtion Communications

First Communications®
Be heard.

IMPORTANT INFORMATION REGARDING YOUR TELECOMMUNICATIONS SERVICE

June 7, 2005

Dear Josephine,

We are happy to share some exciting news about your telephone service. For more than a year, First Communications LLC has been providing underlying long distance service to ACCtion Communications and its customers. We are proud to announce that beginning July 15, 2005, ACCtion Communications local and long distance services will be provided directly by First Communications.

What does this mean?
You will continue to receive the excellent quality you're already receiving on your calls. Plus, all of the great things that you have come to expect from ACCtion Communications will remain the same for the near future. There will be **NO** interruption in service, **NO** change to your rates, service options, or the way that you dial. Notice of any future changes in rates, terms and conditions of service will be provided to you as required by law. In addition, you will still have access to excellent customer care representatives.

First Communications anticipates that the date for the transfer will be July 15, 2005, provided that the necessary regulatory approvals have been obtained. As of that date, ACCtion Communications will no longer be your service provider; instead, your service will be provided by First Communications. First Communications is confident that you will find that remaining with us is the smart choice to meet your needs; however, First Communications realizes that you have a choice of telecommunications carriers, and you may choose another carrier at any point. If you have not notified us that you have arranged with another carrier for service to commence on or before the date ACCtion Communications transfers your service to First Communications, you will automatically become a First Communications customer. You are hereby notified that your customer service agreement will be assigned to First Communications on the date First Communications becomes your service provider, as described in this letter, anticipated to be July 15, 2005.

If you have placed a "freeze" on your ACCtion services to prevent their unauthorized transfer to another carrier, it will be automatically lifted to implement the transfer to First Communications. At your request, First Communications will reestablish the freeze protection for you after the transfer.

Will I be charged for this change?
Absolutely **NOT!** There will be no charge or fee as a result of this change. The only difference that you will notice will be the name of your carrier and the look of your new monthly bill.

Who is First Communications?
For more than 20 years, First Communications has been an innovative company committed to providing excellent service, savings and choices you expect from a full service provider. For more information about First Communications LLC, please visit our website – www.firstcomm.com. Included with this letter is a copy of First Communications Terms and Conditions. To locate a copy or check for updates please visit our website, or watch for inserts in your monthly bill.

First Communications has your information as follows:

JOSEPHINE FLITCRAFT
4219 THIRD ST NW
CANTON OH 44708

Main Number: 330-477-3824
Long Distance: 7.5 cents/minute for all calls within continental U.S. No monthly fee.
ClockStopper: 99 cents for calls within the continental U.S for for 3 hours No charge if under a minute. No monthly fee.

If there is a need to update the above information or if you have any questions you can continue to call ACCtion Communications at 888.655.4222 or you can call direct to First Communications at 1.800.274.1015. **Welcome** to First Communications!

Sincerely,

John Horning

John Horning, President, ACCtion Communications

Ray Hexamer

Ray Hexamer, President, First Communications

*For those customers that have PIC freeze on your local service and wish to switch to a different LD provider you must first remove the PIC with your local service provider and update your PIC information and renew your PIC freeze.

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

In the Matter of	)
	)
DexCom, Inc.	)
	)
Request for Waiver of the Frequency	)
Monitoring Requirements of the	)
Medical Implant Communications	)
Service Rules	)
	)
Expedited Action Requested	)

05-213

REQUEST FOR WAIVER

Henry Goldberg
Laura A. Stefani
Goldberg, Godles, Wiener & Wright
1229 Nineteenth Street, N.W.
Washington, DC 20036
(202) 429-4900
Its Attorneys

May 23, 2005

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Summary

- Diabetes is a serious and costly public health problem. It is estimated that there are 20 million diabetics in the United States. Diabetes is a chronic, life-threatening disease that is the fifth leading cause of death by disease in the United States. One out of every ten health care dollars spent in the United States goes towards diabetes care and the per capita health care cost of a diabetic is five times that of a non-diabetic. In 2002, the cost of diabetes in the United States was estimated to be $132 billion, including $90 billion in direct medical care costs.

- There is no known cure for diabetes; the primary thrust of the medical community in limiting the life-threatening complications of the disease is to have patients effectively monitor and control their blood sugar levels. Studies have shown, however, that patients are having extreme difficulty doing so because the only present methodology for doing so - "finger sticking" - is not a convenient and reliable method to monitor blood glucose levels regularly throughout the day, which would enable patients to adjust their diet, insulin or medication(s) to maintain a proper blood glucose level. Thus, there is a great public need for implantable blood glucose sensors, which can provide continuous, reliable and useful blood glucose information. In fact, Congressional findings in the Food and Drug Administration Modernization Act of 1997, call for development of implantable blood glucose monitoring devices.

- DexCom has developed a breakthrough implantable blood glucose monitoring system, allowing convenient and low cost control of the disease up to now not possible. Clinical studies show that DexCom's system increases the amount of time patients spend at their target blood glucose level by 88%. DexCom's system, expected to cost less than $30 for the short term sensor, represents a low-cost, medically-valuable and efficient alternative to presently-available blood glucose monitoring techniques. Bringing DexCom's blood glucose monitoring devices to market as soon as possible will reap enormous public heath benefits.

- To do so, however, DexCom requires a waiver of the Commission's Medical Implant Communications Service ("MICS") rules, specifically Section 95.628(a), to build and market its system, as the MICS rules require a listen-before-transmit regime that is impossible to build into DexCom's medical implants. Absent a waiver, millions of Americans will be denied what clinical studies have shown is the best way to manage blood sugar levels and avoid complications

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

In the Matter of	)
	)
DexCom, Inc.	)
	)
Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules	)
	)
Expedited Action Requested	)

REQUEST FOR WAIVER

DexCom, Inc. ("DexCom"), by its attorneys and pursuant to Section 1.925 of the Commission's rules,[1] hereby requests a waiver of the frequency monitoring requirements of the Medical Implant Communications Service ("MICS") rules to allow its blood glucose monitoring system to transmit periodically without "listening" before transmitting.[2] DexCom's system is comprised of two devices: a short-term blood glucose monitoring sensor device (STS) and a long-term blood glucose monitoring sensor device (LTS).

DexCom requests that this waiver request be expedited so that diabetics may receive the medical benefits of the periodic transmission mode, which is an essential element of DexCom's blood glucose monitoring technology. DexCom already has requested Food and Drug Administration (FDA) pre-market approval (PMA) for its STS, which it could receive as early as September.[3] DexCom also plans to request PMA for its LTS by early next year. Given the serious health and financial

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[1] 47 C.F.R. § 1.925.
[2] 47 C.F.R. § 95.628(a).
[3] FDA recently granted DexCom expedited review of its PMA in part because of the significant public health concerns of diabetes.

consequences of diabetics failing to manage their glucose levels adequately, the medical community and diabetic patients are anxious to have access to the DexCom system as soon as possible.[4] Accordingly, DexCom requests the Commission act expeditiously so that DexCom can move to market these devices immediately upon FDA approval.

I. BACKGROUND

Diabetes is a serious and costly public health problem, both in the United States and worldwide.[5] It is estimated that there are 20 million diabetics in the United States and more than 171 million diabetics worldwide. Diabetes is a chronic, life-threatening disease that is the fifth leading cause of death by disease in the United States. One out of every ten health care dollars spent in the United States goes towards diabetes care and the per capita health care cost of a diabetic is five times that of a non-diabetic.[6] In 2002, the cost of diabetes in the United States was estimated to be $132 billion, including $90 billion in direct medical care costs.[7] Given that some of these costs are funded by the government, through its Medicaid and Medicare programs, for example, the government obviously has an incentive to find ways to control the disease and reduce these costs.

In part, diabetes' impact on health care costs arises because the disease, if not controlled properly, can lead to severe complications such as heart disease, stroke, loss of kidney function, loss of consciousness, blindness, and amputation of limbs.

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[4] A first-of-its-kind Report released May 18, 2005,by the American Association of Clinical Endocrinologists (AACE) revealed that from 2003 to 2004, two out of three Americans with type 2 diabetes, analyzed in a study of more than 157,000 patients, were not in control of their blood sugar, failing to meet AACE's target A1C goal of 6.5% or less. *See State of Diabetes in America*, Report and Patient Survey, American Assoc. of Clinical Endocrinologists (May 2005), available at www.aace.com.

[5] *See* Diabetics Underestimate Risks, Wall Street Journal (May 19, 2005) (noting that most diabetics are doing a poor job controlling the disease, behavior that leads to serious complications).

[6] *See* www.diabetes.org (official website of the American Diabetes Association).

[7] *Id.*

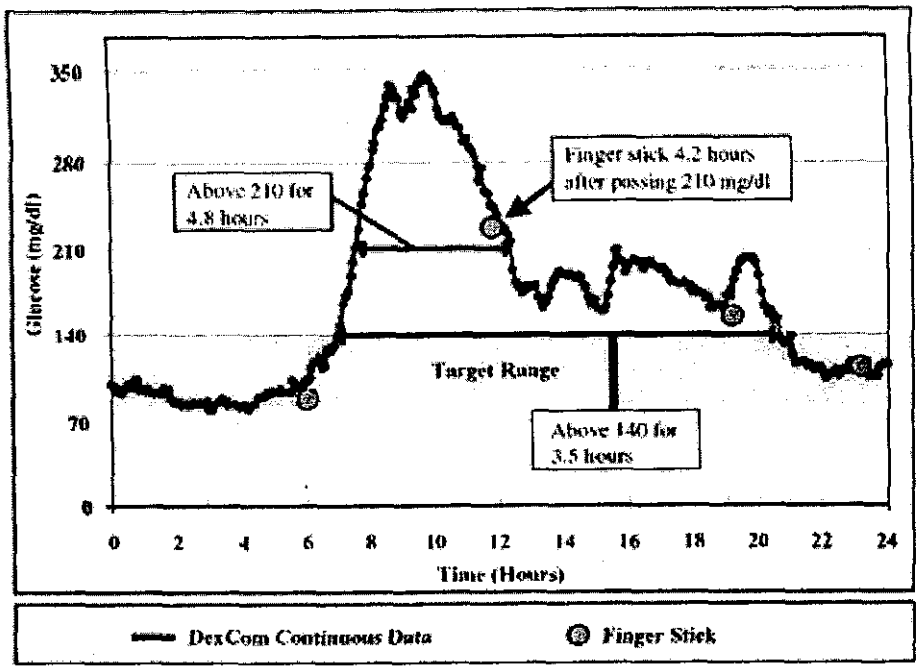
Since there is no known cure, a critical goal of the medical community has been to find a procedure that will permit those suffering from diabetes - both Type 1 and Type 2 diabetes - to manage their blood sugar levels efficiently and reliably and, thus, control their potentially debilitating disease. DexCom's new technology precisely meets this long-elusive goal.

A. THE PROBLEM OF MANAGING DIABETES IN AMERICA.

Research shows that maintaining proper blood glucose levels is the key to controlling diabetes, which in turn greatly reduces the serious long-term complications of the disease. When a patient's blood glucose level is inappropriately too high (hyperglycemic) or too low (hypoglycemic), a patient becomes at greater risk for severe complications. Regular monitoring of blood glucose levels is the *sine qua non* of maintaining constant blood glucose levels and, thereby, greatly reducing the likelihood of the complications of diabetes. A recent national study found that diabetes management has worsened in the past decade and that two-thirds of Type 2 diabetics in America do not have adequate control of their blood glucose levels, which, at present, requires a diabetic to draw a drop of blood from his finger ("finger stick") and then analyze the glucose level of the blood.

A chart summarizing DexCom's clinical trials shows the benefits of continuous blood glucose monitoring. The graph compares the blood glucose level data of a patient using just four finger sticks in one day with the continuous blood glucose level data available from DexCom's system. As the graph indicates, when this patient had access only to the four blood glucose level finger stick data points, the patient's blood glucose level was hyperglycemic for more than half (13.5 hours) of the day.

Single Day Continuous Data



Unfortunately, "finger sticking" is not a convenient and reliable method to monitor blood glucose levels regularly throughout the day, which would enable patients to adjust their diet, insulin or medication(s) to maintain a proper blood glucose level. There are numerous anticipated and unanticipated events that can affect a patient's blood glucose level, such as stress, diet, exercise, illness and hormonal releases. These events can elevate or lower a patient's blood glucose level rapidly and without warning, thereby exposing the patient to potentially dangerous high or low blood glucose levels without providing an opportunity to intervene.

As a practical matter, repeated finger sticking is ineffective for most patients to manage blood glucose levels because of the inconvenience, pain, difficulty and/or lack of information about proper use of finger prick information. Research shows that the average diabetic tests his or her blood glucose level fewer than two times a day. Such infrequent finger sticking provides only isolated points of information regarding the glucose level and does not provide essential trend information, which would be the most valuable information the patient could have. Because of this lack

of blood glucose trend information, most patients are unable to address potentially dangerous changes in their blood glucose levels.

Thus, there is a great public need for implantable blood glucose sensors, which can provide continuous, reliable and useful blood glucose information. In fact, Congressional findings in the Food and Drug Administration Modernization Act of 1997, call for development of implantable blood glucose monitoring devices.[8]

B. DEXCOM'S SOLUTION TO MANAGEMENT OF DIABETES.

DexCom manufactures a system of blood glucose implant devices that have the capability of transmitting blood glucose data continuously. The STS is placed in a patient for up to three days and then the sensor is replaced with a new sensor. The LTS is placed in a patient for up to one year. Both devices use implanted sensors that obtain blood glucose measures, which are then transmitted every five minutes (288 transmissions a day) by wireless RF telemetry to a cell-phone sized receiver that a patient carries with him or her. Patients can, at a push of a button, learn their current blood glucose levels as well as chart their recent blood glucose levels ("trend data") to determine how well they are maintaining constant blood glucose levels.

The frequent transmissions are necessary to allow patients to receive sufficient information regarding their blood glucose levels to monitor and react to those levels by, for example, injecting insulin. The devices allow the collection of a series of blood glucose measurements and trends with a frequency that heretofore has not been possible.

DexCom's devices use two transmission modes: 1) transmission of blood glucose information every five minutes, allowing patients to monitor blood glucose levels over time; and 2) sounding of an alarm when a patient's blood glucose level becomes too high or low. Previously, this type of data essentially was unavailable,

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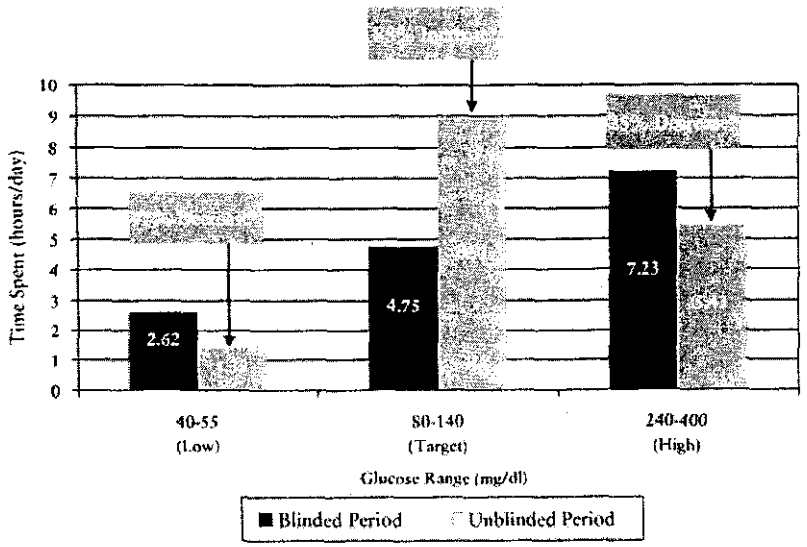
[8] *See* Pub. L. No. 105-115, § 215 (1997).

as collection of it would require a patient to conduct finger prick blood glucose monitoring multiple times throughout the day, something that is both painful and impractical. Clinical studies show that DexCom's system increases the amount of time patients spend at their target blood glucose level by 88%.

The following chart compares the time patients spent at their target blood glucose levels when they were not shown the continuous blood glucose data obtained from the sensors ("blinded period") to when they were given this information ("unblinded period"). When patients had access to the continuous data from the sensors, the amount of time their blood glucose levels were too low decreased by 47%, the amount of time their blood glucose levels were too high decreased by 25%, and the amount of time their blood glucose levels were in the target (normal) range increased by 88%.

Improvement in Glucose Profiles (in 12 of 15 patients)



* $p < 0.05$, indicating statistical significance

DexCom's new technology will enable patients to address changing blood glucose levels themselves, as well as provide valuable information to medical providers regarding the course of a patient's disease. The devices, however, are incapable of satisfying the "listen before transmit" requirement that the MICS rules

impose on all transmissions that do not constitute a "medical implant event." DexCom therefore requires a waiver to permit its system's periodic transmissions to occur.[9]

DexCom's system, expected to cost less than $30 for the STS, represents a low-cost, medically-valuable and efficient alternative to traditional blood glucose monitoring techniques. The periodic transmissions required to conduct this type of monitoring are viewed as highly efficacious by the medical community. In fact, physicians already have written the Commission in support of DexCom's request, indicating the medical community's urgent need for these types of blood glucose monitoring devices.[10] DexCom also receives on a daily basis unsolicited email requests from diabetics requesting use of the devices. As detailed below, the requested waiver is in the public interest and should be granted.

II. GOOD CAUSE EXISTS FOR, AND THE PUBLIC INTEREST WOULD BE SERVED BY, WAIVER OF THE FREQUENCY MONITORING REQUIREMENTS OF THE MICS RULES.

A waiver is warranted under the present circumstances. The Commission has authority to waive its rules if the underlying purpose of the rule would not be served or would be frustrated by application of the rule in the instance case, and waiver of the rule is in the public interest.[11] Such considerations exist in this instance, as the underlying purpose of the MICS service would be frustrated by application of the rule. Grant of the waiver will effectuate the purpose of MICS

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[9] The system's second transmission mode, *i.e.*, sounding an alarm upon dangerously high or low blood glucose levels, is allowed by the medical implant event exception of the rules. *See* 47 C.F.R. § 95.628(b).

[10] *See* Letters to Marlene H. Dortch, Secretary, Federal Communications Commission, from Lois Jovanovic, MD (April 28, 2005); from Steve Edelman, MD (May 3, 2005); and from Sherwin L. Schwartz, MD (May 6, 2005) (all supporting DexCom's blood glucose monitoring devices) (Attached at Appendix A).

[11] 47 C.F.R. § 1.925(b)(3).

rules by enhancing public health[12] and will effectuate the Commission's overall policy of allowing prudent and efficient use of the spectrum.

A. THERE IS NO REALISTIC RISK OF INTERFERENCE CAUSED BY OR TO DEXCOM'S SYSTEM.

DexCom's system represents no risk of interference to other MICS users or to the federal primary users of the 402-405 MHz band. Likewise, DexCom's system is not susceptible to interference that may be caused by such users. The interference concerns underlying the listen before transmit requirement, therefore, would not be served by applying the requirement to DexCom's system.

1. DexCom's System Will Not Interfere With Other MICS Users Or With Primary Users Of The 402-405 MHz Band.

The periodic transmissions emitted by DexCom's medical implant system will not cause harmful interference to other MICS users or to primary federal users of the 402-405 MHz band. Transmissions from DexCom's system occur every five minutes, but last only 6-9 milliseconds each. Moreover, the system has a range of approximately 5 feet[13] and operates at ultra-low power levels, peaking at approximately -20dBm conducted, which is less than the maximum EIRP of 25 microwatts ordinarily authorized for MICS transmitters. The system, moreover, operates on only one frequency - 402.142 MHz.

The operation of DexCom's system in the manner described above does not present any realistic potential for interference to MICS users or to the primary federal users of the 402-405 MHz band. The federal government's principal concern is that transmissions from National Weather Service weather balloons will interfere with DexCom's devices and will, therefore, create life-threatening situations. As

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[12] *See In the Matter of Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules*, 19 FCC Rcd 4208 (2004) (granting a similar waiver on the basis that Biotronik could not serve patient's needs with a fully compliant MICS device).

[13] It is unlikely that other MICS devices will be within 5 feet of the patient.

shown below, there is no realistic risk of such interference or circumstances that could threaten the life of the patient.

2. Other MICS Users And Federal Users Of The 402-405 MHz Band Will Not Interfere With DexCom's System.

There is no realistic risk of interference caused to DexCom's system from other MICS users or from primary users of the 402-405 MHz band, including the National Weather Service weather balloons. In developing its remote monitoring technology, DexCom took into consideration the potential for electromagnetic interference and other sources of noise in the 402-405 MHz band. DexCom did this, in part, because the FDA requires that MICS implants be designed to ensure that interference from impulse, narrowband and broadband systems in the 402-405 MHz band do not affect the ordinary function of the devices or their transmissions.[14]

DexCom's devices have gone through rigorous, FDA-approved testing and will not be marketed until they have received FDA approval. Accordingly, there is no risk that interference from other users of the 402-405 MHz band will cause DexCom's system to malfunction in a manner that would threaten the health and safety of the implant patient.[15]

DexCom has incorporated several protections into its system to ensure the integrity of transmissions. Each sensor has a unique identification code that is included in every transmission from an STS or LTS. In addition, every transmission contains a cyclic redundancy code to validate all transmitted data. The receiver and the sensor are synchronized in time and the receiver channel is active only when it is expecting a transmission from the sensor. If a transmission is lost due to

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[14] As a "fail-safe," FDA will require that patients using the devices also conduct regular finger prick blood glucose testing.

[15] All of DexCom's products are verified to be immune to all sources of electronic noise through exhaustive testing to regulatory standards. These include IEC 60601-1-2 International standard for electromagnetic compatibility for medical electronic equipment, and CISPR11/EN55011, the International Special Committee on Radio Interference standards for electromagnetic radio.

interference, the receiver indicates to the user that the transmission was missed and the receiver does not display data to the patient until a valid DexCom sensor transmission is received.

Finally, even in the unlikely event that a transmission from one of DexCom's devices is unsuccessful due to interference from other users of the 402-405 MHz band, such failure will not affect the health or safety of the implant patient. Simply put, DexCom's STS and LTS are not life sustaining devices and are not intended to take the place of traditional emergency health intervention services. The primary purpose of scheduled periodic messaging is to provide the patient with trend data on his or her blood glucose level and to alert the patient when that level is too high or too low. DexCom's remote messaging technology provides no direct therapy. Indeed, the expected FDA approval will be approval of the DexCom system as a complement to finger sticks.

While the transmitted data from DexCom's implants have substantial medical value, the loss of even a significant number of transmissions out of a total of 288 transmissions a day will not adversely affect the health or safety of the patient. As noted above, the devices are designed to not display any faulty information caused by interference. As well, even if some data collection is missed because of interference or transmission problems, a patient will still receive sufficient data over the course of a day to ensure that there is no harm to his/her health.[16]

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[16] As well, FDA's requirement that patients continue to conduct finger prick testing while using the devices also will assure that patients receive all data needed to control their blood glucose levels.

B. REQUIRING COMPLIANCE WITH THE FREQUENCY MONITORING REQUIREMENTS OF THE MICS RULES WOULD IMPOSE AN UNDUE HARDSHIP ON DEXCOM AND WOULD NOT SERVE THE NEEDS OF PATIENTS.

Absent a waiver, DexCom will not be able to market its blood glucose monitoring system. The technology does not exist to allow DexCom to create a compliant system, namely by incorporating bi-directional technology in its devices to provide periodic transmissions in compliance with the MICS frequency monitoring requirements.

The unidirectional circuitry contained in DexCom's system allows for a compact implant design that offers the value-added feature of remote monitoring. The addition of a bi-directional circuit using present-day technology would upset both of these efficiencies and render DexCom's system unusable. In order to accommodate the extra circuitry necessary to achieve bi-directional capabilities in its system, DexCom would have to increase substantially the size of the circuit board in each implant. As a result, the overall dimensions of the implants themselves would have to be increased substantially, making the devices far too large and heavy for their intended use. Smaller, lightweight devices are necessary to ensure the sensors remain stationary in the body; if it is not stationary, the sensor will not provide an accurate reading of blood glucose levels.

Accordingly, mandating compliance with the frequency monitoring requirements of the MICS rules would deprive diabetics of a long-awaited, low-cost, medically effective and commercially viable technology. When weighed against the negligible risk of interference from or to periodic transmissions, a denial of DexCom's waiver request would be an unnecessary and costly imposition upon the millions of America's diabetics. Such a decision also would disproportionately adversely impact low-income Americans, who suffer from diabetes to a greater

degree and frequency than other Americans.[17] The low cost of DexCom's system would allow even low-income diabetics to manage their disease effectively and inexpensively, a benefit both to them and to the health care system as a whole. For the foreseeable future, the only way diabetics will receive the considerable therapeutic benefits associated with DexCom's system is if the Commission grants the instant request for waiver.

C. WAIVER IS CONSISTENT WITH THE OBJECTIVES OF THE MICS RULES AND WITH THE PUBLIC INTEREST.

The purpose of the medical implant rules is to make the diagnostic and therapeutic benefits of medical implant devices available to the public while avoiding harmful interference.[18] DexCom's implant system furthers these purposes.

As discussed above, periodic transmissions provide medically valuable trending data and other information that enable patients to control blood glucose levels and allow physicians to care for their patients more efficiently and effectively. Strict application of the frequency monitoring requirements of the MICS rules to DexCom's system would deprive diabetics of the only technology capable of enabling them to manage their disease safely, efficiently, reliably, and on a cost-effective basis.

Moreover, as also demonstrated above, there is no realistic risk of interference to or from DexCom's system. Thus, DexCom's system, even without frequency monitoring capabilities, serves both primary goals of the MICS rules.

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[17] *See, e.g., Disparities in Diabetes*, American Public Health Association (April 2004), available at www.apha.org/NPHW/Facts/diabetes-PHW04_facts.pdf (noting that lower income diabetics have higher rates of hospitalization than higher income patients); *Socioeconomic Status of Women with Diabetes – United States, 2000*, Journal of the American Medical Assoc., Vol. 287, No. 19 (May 15, 2002) (finding that women with diabetes were more likely to be of a lower socioeconomic status than non-diabetic women).

[18] *See generally In the Matter of Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band*, Report and Order, 14 FCC Rcd 21040 (1999).

The Commission already has found that waiver of its MICS periodic transmission rules is appropriate under similar circumstances. More than a year ago, the Commission waived its rules to allow Biotronik's cardiac implant devices to operate using periodically scheduled transmissions.[19] As with DexCom's system, Biotronik's system makes periodic transmissions to a hand-held receiver. Like DexCom, Biotronik was unable to engineer a bi-directional device and absent a waiver patients and the medical community would have been denied use of a valuable tool. The Commission found that, given the significant medical value of the transmissions and the showing that there likely would not be harmful interference, a waiver was in the public interest.[20] The same considerations apply in this instance.

III. CONCLUSION

For the foregoing reasons, good cause exists for, and the public interest would be served by, the immediate grant of DexCom's request for a permanent waiver of the frequency monitoring requirements of the MICS rules. DexCom

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[19] *See Biotronik Waiver*, 19 FCC Rcd 4208.

[20] Since that waiver, Biotronik's devices, which also do not have frequency monitoring capability, have coexisted successfully in the 402-405 MHz band with other MICS operators and primary federal users of the band..

respectfully requests that the Commission act expeditiously to grant its waiver request so that diabetics may receive soon the medical benefits of its groundbreaking blood glucose monitoring system.

Respectfully submitted,

DexCom, Inc.

By: _____
Henry Goldberg
Laura A. Stefani

Goldberg, Godles, Wiener & Wright
1229 Nineteenth Street, N.W.
Washington, DC 20036
(202) 429-4900
Its Attorneys

May 23, 2005

APPENDIX A

SANSUM DIABETES RESEARCH INSTITUTE

2219 Bath Street, Santa Barbara, CA 93105 (805) 682-7638 Fax: 682-3332
www.sansum.org email: info@sansum.org Federal tax ID #95-1684086

April 28, 2005

Ms. Marlene H. Dortch
Secretary
Federal Communications Commission
445 12th Street, S.W.
Washington, D.C. 20554

Re: DexCom Short Term Sensor (STS) Continuous Glucose Monitor Support for FCC Authorization

Dear Ms. Dortch:

I am writing in support of the Federal Communication Commission's ("FCC") authorization of the use of DexCom's Short Term Sensor Continuous Glucose Monitor ("STS"). I respectfully urge the Commission to do whatever is necessary to allow DexCom to market and sell its STS device, which is needed to provide diabetics with a unique and meaningful method of monitoring and maintaining level blood glucose levels.

I am a Board certified Endocrinologist who specializes in caring for diabetic patients. In addition, my subspecialty is the management of type 1 diabetic women and helping them achieve as near normal glucose levels as possible to enable them to plan a pregnancy. I am also The Director and Chief Scientific Officer at The Sansum Diabetes Research Institute, Adjunct Professor of Biomolecular Science and Engineering at The University of California-Santa Barbara, and clinical Professor of Medicine at The University of Southern California-Los Angeles. As such, I am involved on a daily basis with addressing the needs of patients monitoring their blood glucose levels. In the filed of diabetes and pregnancy, I care for over three hundred pregnant diabetic women a year and am responsible for supervising their diabetes care protocols. In addition, we have collaborated with DexCom to study the new STS device and have had the opportunity to test the device in clinical trials with type 1 diabetic patients. In this way, I have become familiar with the new DexCom STS device.

DexCom needs the Commission's authority to allow the STS device to operate on the Medical Implant Communications Service ("MICS") frequency using periodic transmissions. The STS device is designed to transmit information regarding a patient's blood glucose level to a hand-held receiver on a regular schedule. Such transmissions are necessary to allow patients to receive sufficient information regarding their blood glucose levels to monitor and react to those levels properly. Unfortunately, most patients currently do not have access to methods to monitor blood glucose levels regularly

throughout the day, which would allow them to adjust their diet, insulin or medication(s) to maintain a proper blood glucose level.

The provision of regularly scheduled blood glucose measurements and data are mandatory to protecting the patients from adverse hyper- or hypoglycemic blood glucose levels that pose a real danger to the life and quality of life of many diabetics. Diabetes has reached epidemic proportions and the cost of diabetes care in the United States has been estimated at $132 billion by the American Diabetes Association. The federally funded Diabetes Control and Complications Trial proved that tighter glucose control can reduce the costly and debilitating complications associated with Diabetes. Thus, I fully support the FCC allowing the use of periodic, scheduled transmissions for DexCom's STS device.

Please feel free to contact me if I can provide any additional information with regard to this matter.

Sincerely yours,

Lois Jovanovic, MD

Lois Jovanovic, MD
Director and Chief Scientific Officer
Sansum Diabetes Research Institute
Adjunct Professor of Biomolecular Science and Engineering
University of California-Santa Barbara
Clinical Professor of Medicine
University of Southern California-Los Angeles

UNIVERSITY OF CALIFORNIA, SAN DIEGO

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DEPARTMENT OF MEDICINE
SCHOOL OF MEDICINE

VETERANS AFFAIRS MEDICAL CENTER
3350 LA JOLLA VILLAGE DRIVE
SAN DIEGO, CALIFORNIA 92161

May 3, 2005

Ms. Marlene H. Dortch
Secretary
Federal Communications Commission
445 12th Street, S.W.
Washington, D.C. 20554

Re: DexCom Short Term Sensor (STS) Continuous Glucose Monitor Support for FCC Authorization

Dear Ms. Dortch:

I am writing in support of the Federal Communication Commission's ("FCC") authorization of the use of DexCom's Short Term Sensor Continuous Glucose Monitor ("STS"). I respectfully urge the Commission to do whatever is necessary to allow DexCom to market and sell its STS device, which is needed to provide diabetics with a unique and meaningful method of monitoring and maintaining level blood glucose levels.

I am a practicing endocrinologist who specializes in diabetes. I am also a professor of medicine at UCSD and involved in clinical research, teaching outpatient care.. As such, I am involved on a daily basis with addressing the needs of patients monitoring their blood glucose levels and I have a large number of type 1 and insulin requiring type 2 diabetics. In this way, I have become familiar with the new DexCom STS device.

DexCom needs the Commission's authority to allow the STS device to operate on the Medical Implant Communications Service ("MICS") frequency using periodic transmissions. The STS device is designed to transmit information regarding a patient's blood glucose level to a hand-held receiver on a regular schedule. Such transmissions are necessary to allow patients to receive sufficient information regarding their blood glucose levels to monitor and react to those levels properly. Unfortunately, most patients currently do not have access to methods to monitor blood glucose levels regularly throughout the day, which would allow them to adjust their diet, insulin or medication(s) to maintain a proper blood glucose level.

The provision of regularly scheduled blood glucose measurements and data are key to protecting the patients from adverse hyper- or hypoglycemic blood glucose levels that pose a real danger to the life and quality of life of many diabetics. Diabetes has reached epidemic proportions and the cost of diabetes care in the United States has been estimated at $132 billion by the American Diabetes Association. The federally funded Diabetes Control and Complications Trial proved that tighter glucose control can reduce the costly and debilitating complications associated with Diabetes. Thus, I fully support the FCC allowing the use of periodic, scheduled transmissions for DexCom's STS device.

Please feel free to contact me if I can provide any additional information with regard to this matter.

Sincerely yours,

Steve Edelman, M.D.
Professor of Medicine
Division of Endocrinology, Diabetes & Metabolism
University of California San Diego
Veterans Affairs Medical Center

Diabetes & Glandular Disease Clinic, P.A.

SHERWYN L. SCHWARTZ, M.D.
DIPLOMATE
American Board of Internal Medicine
American Board of Endocrinology

AMINA A. SALHIN, M.D.
DIPLOMATE
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JEROME S. FISCHER, M.D.
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JACOB VADAKEKALAM, M.D.
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MARK S. KIPNES, M.D.
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MARK M. DANNEY, M.D.
DIPLOMATE
American Board of Pediatrics
American Board of Pediatric Endocrinology

W. FERNANDO TRIGOSO, M.D.
DIPLOMATE
American Board of Internal Medicine
American Board of Endocrinology

MICHELLE D. WELCH, M.D.
DIPLOMATE
American Board of Internal Medicine
American Board of Endocrinology

May 6, 2005

Ms. Marlene H. Dortch
Secretary
Federal Communications Commission
445 12th Street, S.W.
Washington, D.C. 20554

Re: DexCom Short Term Sensor (STS) Continuous Glucose Monitor Support for FCC Authorization

Dear Ms. Dortch:

I am writing in support of the Federal Communication Commission's ("FCC") authorization of the use of DexCom's Short Term Sensor Continuous Glucose Monitor ("STS"). I respectfully urge the Commission to do whatever is necessary to allow DexCom to market and sell its STS device, which is needed to provide diabetics with a unique and meaningful method of monitoring and maintaining level blood glucose levels.

I am a practicing board-certified endocrinologist who specializes in diabetes, endocrinology and metabolism. I am also the founder and medical director of the Diabetes & Glandular Disease Clinic (established in 1979), an eight physician (all board certified endocrinologists) six extender clinical practice with over 60,000 active patients and a research unit specializing in endocrinology which employs over 200 people and has conducted over 700 Phase I through III clinical trials. I hold the following Professional Appointments:

National Advisor for Diabetes to Merck- Medco, 1995 to present
LULAC (League of United Latin American Citizens) National Medical Advisor for Diabetes
Director, Diabetes Center of Excellence, Methodist Specialty & Transplant Hospital (formerly San Antonio Community Hospital), San Antonio, Texas, 1983 – present
Director, Diabetes & Glandular Disease Research Associates, San Antonio, Texas, 1983 – present.
Director, Diabetes & Glandular Disease Clinic, San Antonio, Texas, 1979 – present

I hold or have held the following Academic Appointments:

Clinical Professor – Medicine/General Medicine. The University of Texas Health Science Center at San Antonio. From September 1, 2001 through August 31, 2003.
Reviewer for *Diabetes Care*. 1995 to present.
Endocrinology Consultant, Brook Army Medical Center, Fort Sam Houston, Texas, 1979 - 1985
Assistant Professor of Endocrinology, University of Texas Health Science Center, San Antonio,

TEL 210•614•8612
FAX 210•615•1666

5107 Medical Drive ■ San Antonio, Texas ■ 78229-4801
Clinical Practice ■ Clinical Research ■ Diabetic Education Center
Visit Our Website @: www.dgdclinic.com

Texas, 1979 - 1981
Instructor, St. Luke's Presbyterian Hospital, Chicago, Illinois, 1976 – 1977

I am involved in the following Professional Activities:

Keryx Biopharmaceuticals, Overt and Micro Trials - Executive Committee/Recruitment Committee
Takeda Pharmaceuticals America, Inc. Actos™ Speakers Bureau, current
Bayer Consultants Advisory Board, current
Purdue Pharma Consultant Advisory Board, current
Lilly Device Consultants Advisory Board, current
Pharmacia & Upjohn Advisory Board, current
Merck-Medco Advisory Board, current
Parke-Davis Troglitazone Advisory Board, past
Diabetes Forecast Editorial Advisory Board, current
Quality Outcomes In Diabetes Editorial Advisory Board, current
Member, Glipizide Symposium, Roerig- Pfizer, 1983 - 1986
Advisory Committee, Upjohn Company, 1984
Humulin Advisory Committee, Eli Lilly & Company, 1984
American College of Physicians, current
American Diabetes Foundation, San Antonio Chapter, Medical Advisory Board, current
Juvenile Diabetes Foundation, San Antonio Chapter, Medical Advisory Board, current
San Antonio Endocrinology Club, current
San Antonio Internists Club, current
American Diabetes Association, current
Texas Diabetes Association, current
The Endocrine Society (former President), current
Bexar County Medical Society, current

I hold the position of Staff Physician in the following institutions:

1999 – Present	CHRISTUS Santa Rosa Medical Center 2827 Babcock Road San Antonio, Texas 78229
1979 – present	Methodist Specialty and Transplant Hospital (Formerly San Antonio Community Hospital) 8026 Floyd Curl Drive San Antonio, Texas 78229
1979 – present	Southwest Texas Methodist Hospital 7700 Floyd Curl Drive San Antonio, Texas 78229
1979 – present	St. Luke's Baptist Hospital 7930 Floyd Curl Drive San Antonio, Texas 78229

1979 – present	Methodist Children's Hospital (Formerly Methodist Women's & Children's Hospital) 7700 Floyd Curl Drive San Antonio, Texas 78229
1977 to 1979	Assistant Chief of Endocrinology BAMC Fort Sam Houston, Texas 78234

I have also authored or co-authored over 100 scientific abstracts regarding diabetes, diabetes treatment, diabetes research and diabetes device testing.

As such, I am involved on a daily basis with addressing the needs of patients monitoring their blood glucose levels. In my clinical practice I see over 500 patients per month in the office and hospital and am Principal Investigator on numerous Phase I – III clinical trials for diabetic states In this way, I have become familiar with the new DexCom STS device.

DexCom needs the Commission's authority to allow the STS device to operate on the Medical Implant Communications Service ("MICS") frequency using periodic transmissions. The STS device is designed to transmit information regarding a patient's blood glucose level to a hand-held receiver on a regular schedule. Such transmissions are necessary to allow patients to receive sufficient information regarding their blood glucose levels to monitor and react to those levels properly. Unfortunately, most patients currently do not have access to methods to monitor blood glucose levels regularly throughout the day, which would allow them to adjust their diet, insulin or medication(s) to maintain a proper blood glucose level.

The provision of regularly scheduled blood glucose measurements and data are key to protecting the patients from adverse hyper- or hypoglycemic blood glucose levels that pose a real danger to the life and quality of life of many diabetics. Diabetes has reached epidemic proportions and the costs of diabetes care in the United States has been estimated at $132 billion by the American Diabetes Association. The federally funded Diabetes Control and Complications Trial proved that tighter glucose control can reduce the costly and debilitating complications associated with Diabetes. Thus, I fully support the FCC allowing the use of periodic, scheduled transmissions for DexCom's STS device.

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

In the Matter of	)
	)
DexCom, Inc.	)
	)
Request for Waiver of the Frequency	)
Monitoring Requirements of the	)
Medical Implant Communications	)
Service Rules	)
	)
Expedited Action Requested	)

05-213

REQUEST FOR WAIVER

Henry Goldberg
Laura A. Stefani
Goldberg, Godles, Wiener & Wright
1229 Nineteenth Street, N.W.
Washington, DC 20036
(202) 429-4900
Its Attorneys

May 23, 2005

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Summary

- Diabetes is a serious and costly public health problem. It is estimated that there are 20 million diabetics in the United States. Diabetes is a chronic, life-threatening disease that is the fifth leading cause of death by disease in the United States. One out of every ten health care dollars spent in the United States goes towards diabetes care and the per capita health care cost of a diabetic is five times that of a non-diabetic. In 2002, the cost of diabetes in the United States was estimated to be $132 billion, including $90 billion in direct medical care costs.

- There is no known cure for diabetes; the primary thrust of the medical community in limiting the life-threatening complications of the disease is to have patients effectively monitor and control their blood sugar levels. Studies have shown, however, that patients are having extreme difficulty doing so because the only present methodology for doing so - "finger sticking" - is not a convenient and reliable method to monitor blood glucose levels regularly throughout the day, which would enable patients to adjust their diet, insulin or medication(s) to maintain a proper blood glucose level. Thus, there is a great public need for implantable blood glucose sensors, which can provide continuous, reliable and useful blood glucose information. In fact, Congressional findings in the Food and Drug Administration Modernization Act of 1997, call for development of implantable blood glucose monitoring devices.

- DexCom has developed a breakthrough implantable blood glucose monitoring system, allowing convenient and low cost control of the disease up to now not possible. Clinical studies show that DexCom's system increases the amount of time patients spend at their target blood glucose level by 88%. DexCom's system, expected to cost less than $30 for the short term sensor, represents a low-cost, medically-valuable and efficient alternative to presently-available blood glucose monitoring techniques. Bringing DexCom's blood glucose monitoring devices to market as soon as possible will reap enormous public heath benefits.

- To do so, however, DexCom requires a waiver of the Commission's Medical Implant Communications Service ("MICS") rules, specifically Section 95.628(a), to build and market its system, as the MICS rules require a listen-before-transmit regime that is impossible to build into DexCom's medical implants. Absent a waiver, millions of Americans will be denied what clinical studies have shown is the best way to manage blood sugar levels and avoid complications

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REQUEST FOR WAIVER

DexCom, Inc. ("DexCom"), by its attorneys and pursuant to Section 1.925 of the Commission's rules,[1] hereby requests a waiver of the frequency monitoring requirements of the Medical Implant Communications Service ("MICS") rules to allow its blood glucose monitoring system to transmit periodically without "listening" before transmitting.[2] DexCom's system is comprised of two devices: a short-term blood glucose monitoring sensor device (STS) and a long-term blood glucose monitoring sensor device (LTS).

DexCom requests that this waiver request be expedited so that diabetics may receive the medical benefits of the periodic transmission mode, which is an essential element of DexCom's blood glucose monitoring technology. DexCom already has requested Food and Drug Administration (FDA) pre-market approval (PMA) for its STS, which it could receive as early as September.[3] DexCom also plans to request PMA for its LTS by early next year. Given the serious health and financial

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[1] 47 C.F.R. § 1.925.
[2] 47 C.F.R. § 95.628(a).
[3] FDA recently granted DexCom expedited review of its PMA in part because of the *significant* public health concerns of diabetes.

consequences of diabetics failing to manage their glucose levels adequately, the medical community and diabetic patients are anxious to have access to the DexCom system as soon as possible.[4] Accordingly, DexCom requests the Commission act expeditiously so that DexCom can move to market these devices immediately upon FDA approval.

I. BACKGROUND

Diabetes is a serious and costly public health problem, both in the United States and worldwide.[5] It is estimated that there are 20 million diabetics in the United States and more than 171 million diabetics worldwide. Diabetes is a chronic, life-threatening disease that is the fifth leading cause of death by disease in the United States. One out of every ten health care dollars spent in the United States goes towards diabetes care and the per capita health care cost of a diabetic is five times that of a non-diabetic.[6] In 2002, the cost of diabetes in the United States was estimated to be $132 billion, including $90 billion in direct medical care costs.[7] Given that some of these costs are funded by the government, through its Medicaid and Medicare programs, for example, the government obviously has an incentive to find ways to control the disease and reduce these costs.

In part, diabetes' impact on health care costs arises because the disease, if not controlled properly, can lead to severe complications such as heart disease, stroke, loss of kidney function, loss of consciousness, blindness, and amputation of limbs.

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[4] A first-of-its-kind Report released May 18, 2005,by the American Association of Clinical Endocrinologists (AACE) revealed that from 2003 to 2004, two out of three Americans with type 2 diabetes, analyzed in a study of more than 157,000 patients, were not in control of their blood sugar, failing to meet AACE's target A1C goal of 6.5% or less. *See State of Diabetes in America*, Report and Patient Survey, American Assoc. of Clinical Endocrinologists (May 2005), available at www.aace.com.

[5] *See* Diabetics Underestimate Risks, Wall Street Journal (May 19, 2005) (noting that most diabetics are doing a poor job controlling the disease, behavior that leads to serious complications).

[6] *See* www.diabetes.org (official website of the American Diabetes Association).

[7] *Id.*

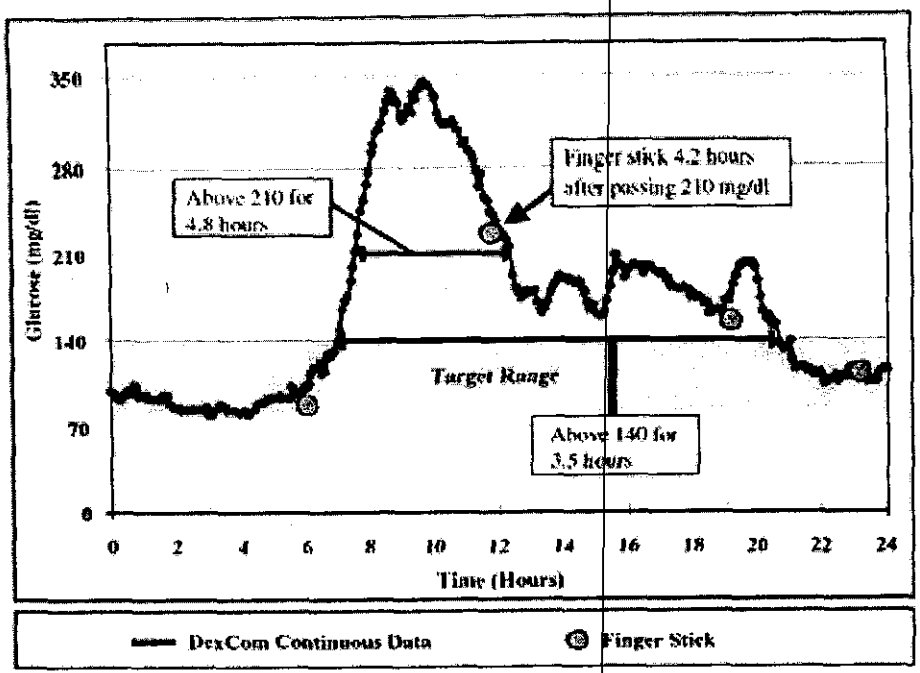
Since there is no known cure, a critical goal of the medical community has been to find a procedure that will permit those suffering from diabetes - both Type 1 and Type 2 diabetes - to manage their blood sugar levels efficiently and reliably and, thus, control their potentially debilitating disease. DexCom's new technology precisely meets this long-elusive goal.

A. THE PROBLEM OF MANAGING DIABETES IN AMERICA.

Research shows that maintaining proper blood glucose levels is the key to controlling diabetes, which in turn greatly reduces the serious long-term complications of the disease. When a patient's blood glucose level is inappropriately too high (hyperglycemic) or too low (hypoglycemic), a patient becomes at greater risk for severe complications. Regular monitoring of blood glucose levels is the *sine qua non* of maintaining constant blood glucose levels and, thereby, greatly reducing the likelihood of the complications of diabetes. A recent national study found that diabetes management has worsened in the past decade and that two-thirds of Type 2 diabetics in America do not have adequate control of their blood glucose levels, which, at present, requires a diabetic to draw a drop of blood from his finger ("finger stick") and then analyze the glucose level of the blood.

A chart summarizing DexCom's clinical trials shows the benefits of continuous blood glucose monitoring. The graph compares the blood glucose level data of a patient using just four finger sticks in one day with the continuous blood glucose level data available from DexCom's system. As the graph indicates, when this patient had access only to the four blood glucose level finger stick data points, the patient's blood glucose level was hyperglycemic for more than half (13.5 hours) of the day.

Single Day Continuous Data



Unfortunately, "finger sticking" is not a convenient and reliable method to monitor blood glucose levels regularly throughout the day, which would enable patients to adjust their diet, insulin or medication(s) to maintain a proper blood glucose level. There are numerous anticipated and unanticipated events that can affect a patient's blood glucose level, such as stress, diet, exercise, illness and hormonal releases. These events can elevate or lower a patient's blood glucose level rapidly and without warning, thereby exposing the patient to potentially dangerous high or low blood glucose levels without providing an opportunity to intervene.

As a practical matter, repeated finger sticking is ineffective for most patients to manage blood glucose levels because of the inconvenience, pain, difficulty and/or lack of information about proper use of finger prick information. Research shows that the average diabetic tests his or her blood glucose level fewer than two times a day. Such infrequent finger sticking provides only isolated points of information regarding the glucose level and does not provide essential trend information, which would be the most valuable information the patient could have. Because of this lack

of blood glucose trend information, most patients are unable to address potentially dangerous changes in their blood glucose levels.

Thus, there is a great public need for implantable blood glucose sensors, which can provide continuous, reliable and useful blood glucose information. In fact, Congressional findings in the Food and Drug Administration Modernization Act of 1997, call for development of implantable blood glucose monitoring devices.[8]

B. DexCom's Solution to Management of Diabetes.

DexCom manufactures a system of blood glucose implant devices that have the capability of transmitting blood glucose data continuously. The STS is placed in a patient for up to three days and then the sensor is replaced with a new sensor. The LTS is placed in a patient for up to one year. Both devices use implanted sensors that obtain blood glucose measures, which are then transmitted every five minutes (288 transmissions a day) by wireless RF telemetry to a cell-phone sized receiver that a patient carries with him or her. Patients can, at a push of a button, learn their current blood glucose levels as well as chart their recent blood glucose levels ("trend data") to determine how well they are maintaining constant blood glucose levels.

The frequent transmissions are necessary to allow patients to receive sufficient information regarding their blood glucose levels to monitor and react to those levels by, for example, injecting insulin. The devices allow the collection of a series of blood glucose measurements and trends with a frequency that heretofore has not been possible.

DexCom's devices use two transmission modes: 1) transmission of blood glucose information every five minutes, allowing patients to monitor blood glucose levels over time; and 2) sounding of an alarm when a patient's blood glucose level becomes too high or low. Previously, this type of data essentially was unavailable,

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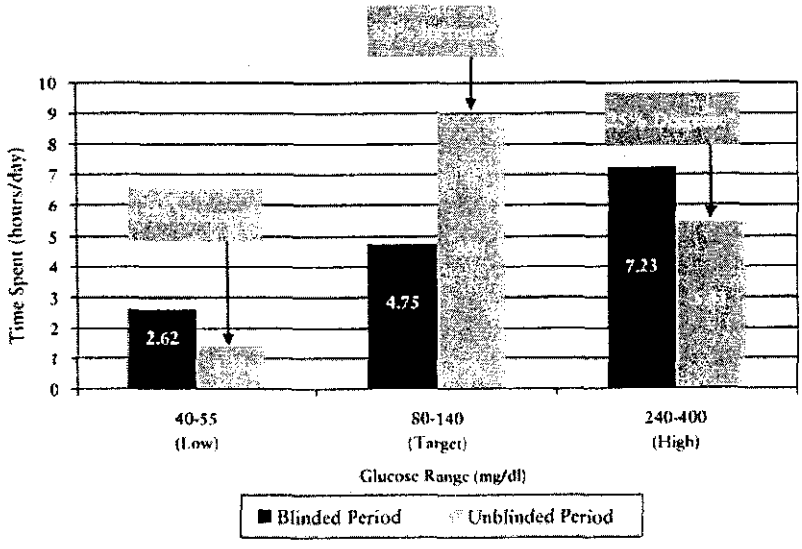
[8] *See* Pub. L. No. 105-115, § 215 (1997).

as collection of it would require a patient to conduct finger prick blood glucose monitoring multiple times throughout the day, something that is both painful and impractical. Clinical studies show that DexCom's system increases the amount of time patients spend at their target blood glucose level by 88%.

The following chart compares the time patients spent at their target blood glucose levels when they were not shown the continuous blood glucose data obtained from the sensors ("blinded period") to when they were given this information ("unblinded period"). When patients had access to the continuous data from the sensors, the amount of time their blood glucose levels were too low decreased by 47%, the amount of time their blood glucose levels were too high decreased by 25%, and the amount of time their blood glucose levels were in the target (normal) range increased by 88%.

Improvement in Glucose Profiles (in 12 of 15 patients)



* $p < 0.05$, indicating statistical significance

DexCom's new technology will enable patients to address changing blood glucose levels themselves, as well as provide valuable information to medical providers regarding the course of a patient's disease. The devices, however, are incapable of satisfying the "listen before transmit" requirement that the MICS rules

impose on all transmissions that do not constitute a "medical implant event." DexCom therefore requires a waiver to permit its system's periodic transmissions to occur.[9]

DexCom's system, expected to cost less than $30 for the STS, represents a low-cost, medically-valuable and efficient alternative to traditional blood glucose monitoring techniques. The periodic transmissions required to conduct this type of monitoring are viewed as highly efficacious by the medical community. In fact, physicians already have written the Commission in support of DexCom's request, indicating the medical community's urgent need for these types of blood glucose monitoring devices.[10] DexCom also receives on a daily basis unsolicited email requests from diabetics requesting use of the devices. As detailed below, the requested waiver is in the public interest and should be granted.

II. GOOD CAUSE EXISTS FOR, AND THE PUBLIC INTEREST WOULD BE SERVED BY, WAIVER OF THE FREQUENCY MONITORING REQUIREMENTS OF THE MICS RULES.

A waiver is warranted under the present circumstances. The Commission has authority to waive its rules if the underlying purpose of the rule would not be served or would be frustrated by application of the rule in the instance case, and waiver of the rule is in the public interest.[11] Such considerations exist in this instance, as the underlying purpose of the MICS service would be frustrated by application of the rule. Grant of the waiver will effectuate the purpose of MICS

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[9] The system's second transmission mode, *i.e.*, sounding an alarm upon dangerously high or low blood glucose levels, is allowed by the medical implant event exception of the rules. *See* 47 C.F.R. § 95.628(b).

[10] *See* Letters to Marlene H. Dortch, Secretary, Federal Communications Commission, from Lois Jovanovic, MD (April 28, 2005); from Steve Edelman, MD (May 3, 2005); and from Sherwin L. Schwartz, MD (May 6, 2005) (all supporting DexCom's blood glucose monitoring devices) (Attached at Appendix A).

[11] 47 C.F.R. § 1.925(b)(3).

rules by enhancing public health[12] and will effectuate the Commission's overall policy of allowing prudent and efficient use of the spectrum.

A. THERE IS NO REALISTIC RISK OF INTERFERENCE CAUSED BY OR TO DEXCOM'S SYSTEM.

DexCom's system represents no risk of interference to other MICS users or to the federal primary users of the 402-405 MHz band. Likewise, DexCom's system is not susceptible to interference that may be caused by such users. The interference concerns underlying the listen before transmit requirement, therefore, would not be served by applying the requirement to DexCom's system.

1. DexCom's System Will Not Interfere With Other MICS Users Or With Primary Users Of The 402-405 MHz Band.

The periodic transmissions emitted by DexCom's medical implant system will not cause harmful interference to other MICS users or to primary federal users of the 402-405 MHz band. Transmissions from DexCom's system occur every five minutes, but last only 6-9 milliseconds each. Moreover, the system has a range of approximately 5 feet[13] and operates at ultra-low power levels, peaking at approximately -20dBm conducted, which is less than the maximum EIRP of 25 microwatts ordinarily authorized for MICS transmitters. The system, moreover, operates on only one frequency - 402.142 MHz.

The operation of DexCom's system in the manner described above does not present any realistic potential for interference to MICS users or to the primary federal users of the 402-405 MHz band. The federal government's principal concern is that transmissions from National Weather Service weather balloons will interfere with DexCom's devices and will, therefore, create life-threatening situations. As

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[12] *See In the Matter of Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules*, 19 FCC Rcd 4208 (2004) (granting a similar waiver on the basis that Biotronik could not serve patient's needs with a fully compliant MICS device).

[13] It is unlikely that other MICS devices will be within 5 feet of the patient.

shown below, there is no realistic risk of such interference or circumstances that could threaten the life of the patient.

2. Other MICS Users And Federal Users Of The 402-405 MHz Band Will Not Interfere With DexCom's System.

There is no realistic risk of interference caused to DexCom's system from other MICS users or from primary users of the 402-405 MHz band, including the National Weather Service weather balloons. In developing its remote monitoring technology, DexCom took into consideration the potential for electromagnetic interference and other sources of noise in the 402-405 MHz band. DexCom did this, in part, because the FDA requires that MICS implants be designed to ensure that interference from impulse, narrowband and broadband systems in the 402-405 MHz band do not affect the ordinary function of the devices or their transmissions.[14]

DexCom's devices have gone through rigorous, FDA-approved testing and will not be marketed until they have received FDA approval. Accordingly, there is no risk that interference from other users of the 402-405 MHz band will cause DexCom's system to malfunction in a manner that would threaten the health and safety of the implant patient.[15]

DexCom has incorporated several protections into its system to ensure the integrity of transmissions. Each sensor has a unique identification code that is included in every transmission from an STS or LTS. In addition, every transmission contains a cyclic redundancy code to validate all transmitted data. The receiver and the sensor are synchronized in time and the receiver channel is active only when it is expecting a transmission from the sensor. If a transmission is lost due to

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[14] As a "fail-safe," FDA will require that patients using the devices also conduct regular finger prick blood glucose testing.

[15] All of DexCom's products are verified to be immune to all sources of electronic noise through exhaustive testing to regulatory standards. These include IEC 60601-1-2 International standard for electromagnetic compatibility for medical electronic equipment, and CISPR11/EN55011, the International Special Committee on Radio Interference standards for electromagnetic radio.

interference, the receiver indicates to the user that the transmission was missed and the receiver does not display data to the patient until a valid DexCom sensor transmission is received.

Finally, even in the unlikely event that a transmission from one of DexCom's devices is unsuccessful due to interference from other users of the 402-405 MHz band, such failure will not affect the health or safety of the implant patient. Simply put, DexCom's STS and LTS are not life sustaining devices and are not intended to take the place of traditional emergency health intervention services. The primary purpose of scheduled periodic messaging is to provide the patient with trend data on his or her blood glucose level and to alert the patient when that level is too high or too low. DexCom's remote messaging technology provides no direct therapy. Indeed, the expected FDA approval will be approval of the DexCom system as a complement to finger sticks.

While the transmitted data from DexCom's implants have substantial medical value, the loss of even a significant number of transmissions out of a total of 288 transmissions a day will not adversely affect the health or safety of the patient. As noted above, the devices are designed to not display any faulty information caused by interference. As well, even if some data collection is missed because of interference or transmission problems, a patient will still receive sufficient data over the course of a day to ensure that there is no harm to his/her health.[16]

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[16] As well, FDA's requirement that patients continue to conduct finger prick testing while using the devices also will assure that patients receive all data needed to control their blood glucose levels.

B. REQUIRING COMPLIANCE WITH THE FREQUENCY MONITORING REQUIREMENTS OF THE MICS RULES WOULD IMPOSE AN UNDUE HARDSHIP ON DEXCOM AND WOULD NOT SERVE THE NEEDS OF PATIENTS.

Absent a waiver, DexCom will not be able to market its blood glucose monitoring system. The technology does not exist to allow DexCom to create a compliant system, namely by incorporating bi-directional technology in its devices to provide periodic transmissions in compliance with the MICS frequency monitoring requirements.

The unidirectional circuitry contained in DexCom's system allows for a compact implant design that offers the value-added feature of remote monitoring. The addition of a bi-directional circuit using present-day technology would upset both of these efficiencies and render DexCom's system unusable. In order to accommodate the extra circuitry necessary to achieve bi-directional capabilities in its system, DexCom would have to increase substantially the size of the circuit board in each implant. As a result, the overall dimensions of the implants themselves would have to be increased substantially, making the devices far too large and heavy for their intended use. Smaller, lightweight devices are necessary to ensure the sensors remain stationary in the body; if it is not stationary, the sensor will not provide an accurate reading of blood glucose levels.

Accordingly, mandating compliance with the frequency monitoring requirements of the MICS rules would deprive diabetics of a long-awaited, low-cost, medically effective and commercially viable technology. When weighed against the negligible risk of interference from or to periodic transmissions, a denial of DexCom's waiver request would be an unnecessary and costly imposition upon the millions of America's diabetics. Such a decision also would disproportionately adversely impact low-income Americans, who suffer from diabetes to a greater

degree and frequency than other Americans.[17] The low cost of DexCom's system would allow even low-income diabetics to manage their disease effectively and inexpensively, a benefit both to them and to the health care system as a whole. For the foreseeable future, the only way diabetics will receive the considerable therapeutic benefits associated with DexCom's system is if the Commission grants the instant request for waiver.

C. WAIVER IS CONSISTENT WITH THE OBJECTIVES OF THE MICS RULES AND WITH THE PUBLIC INTEREST.

The purpose of the medical implant rules is to make the diagnostic and therapeutic benefits of medical implant devices available to the public while avoiding harmful interference.[18] DexCom's implant system furthers these purposes.

As discussed above, periodic transmissions provide medically valuable trending data and other information that enable patients to control blood glucose levels and allow physicians to care for their patients more efficiently and effectively. Strict application of the frequency monitoring requirements of the MICS rules to DexCom's system would deprive diabetics of the only technology capable of enabling them to manage their disease safely, efficiently, reliably, and on a cost-effective basis.

Moreover, as also demonstrated above, there is no realistic risk of interference to or from DexCom's system. Thus, DexCom's system, even without frequency monitoring capabilities, serves both primary goals of the MICS rules.

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[17] *See, e.g., Disparities in Diabetes,* American Public Health Association (April 2004), available at www.apha.org/NPHW/Facts/diabetes-PHW04_facts.pdf (noting that lower income diabetics have higher rates of hospitalization than higher income patients); *Socioeconomic Status of Women with Diabetes – United States, 2000,* Journal of the American Medical Assoc., Vol. 287, No. 19 (May 15, 2002) (finding that women with diabetes were more likely to be of a lower socioeconomic status than non-diabetic women).

[18] *See generally In the Matter of Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band,* Report and Order, 14 FCC Rcd 21040 (1999).

The Commission already has found that waiver of its MICS periodic transmission rules is appropriate under similar circumstances. More than a year ago, the Commission waived its rules to allow Biotronik's cardiac implant devices to operate using periodically scheduled transmissions.[19] As with DexCom's system, Biotronik's system makes periodic transmissions to a hand-held receiver. Like DexCom, Biotronik was unable to engineer a bi-directional device and absent a waiver patients and the medical community would have been denied use of a valuable tool. The Commission found that, given the significant medical value of the transmissions and the showing that there likely would not be harmful interference, a waiver was in the public interest.[20] The same considerations apply in this instance.

III. CONCLUSION

For the foregoing reasons, good cause exists for, and the public interest would be served by, the immediate grant of DexCom's request for a permanent waiver of the frequency monitoring requirements of the MICS rules. DexCom

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[19] *See Biotronik Waiver*, 19 FCC Rcd 4208.

[20] Since that waiver, Biotronik's devices, which also do not have frequency monitoring capability, have coexisted successfully in the 402-405 MHz band with other MICS operators and primary federal users of the band.

respectfully requests that the Commission act expeditiously to grant its waiver request so that diabetics may receive soon the medical benefits of its groundbreaking blood glucose monitoring system.

Respectfully submitted,

DexCom, Inc.

By: _____

Henry Goldberg
Laura A. Stefani

Goldberg, Godles, Wiener & Wright
1229 Nineteenth Street, N.W.
Washington, DC 20036
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Its Attorneys

May 23, 2005

APPENDIX A

SANSUM DIABETES RESEARCH INSTITUTE

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www.sansum.org email: info@sansum.org Federal tax ID #95-1684086

April 28, 2005

Ms. Marlene H. Dortch
Secretary
Federal Communications Commission
445 12th Street, S.W.
Washington, D.C. 20554

Re: DexCom Short Term Sensor (STS) Continuous Glucose Monitor Support for FCC Authorization

Dear Ms. Dortch:

I am writing in support of the Federal Communication Commission's ("FCC") authorization of the use of DexCom's Short Term Sensor Continuous Glucose Monitor ("STS"). I respectfully urge the Commission to do whatever is necessary to allow DexCom to market and sell its STS device, which is needed to provide diabetics with a unique and meaningful method of monitoring and maintaining level blood glucose levels.

I am a Board certified Endocrinologist who specializes in caring for diabetic patients. In addition, my subspecialty is the management of type 1 diabetic women and helping them achieve as near normal glucose levels as possible to enable them to plan a pregnancy. I am also The Director and Chief Scientific Officer at The Sansum Diabetes Research Institute, Adjunct Professor of Biomolecular Science and Engineering at The University of California-Santa Barbara, and clinical Professor of Medicine at The University of Southern California-Los Angeles. As such, I am involved on a daily basis with addressing the needs of patients monitoring their blood glucose levels. In the filed of diabetes and pregnancy, I care for over three hundred pregnant diabetic women a year and am responsible for supervising their diabetes care protocols. In addition, we have collaborated with DexCom to study the new STS device and have had the opportunity to test the device in clinical trials with type 1 diabetic patients. In this way, I have become familiar with the new DexCom STS device.

DexCom needs the Commission's authority to allow the STS device to operate on the Medical Implant Communications Service ("MICS") frequency using periodic transmissions. The STS device is designed to transmit information regarding a patient's blood glucose level to a hand-held receiver on a regular schedule. Such transmissions are necessary to allow patients to receive sufficient information regarding their blood glucose levels to monitor and react to those levels properly. Unfortunately, most patients currently do not have access to methods to monitor blood glucose levels regularly

throughout the day, which would allow them to adjust their diet, insulin or medication(s) to maintain a proper blood glucose level.

The provision of regularly scheduled blood glucose measurements and data are mandatory to protecting the patients from adverse hyper- or hypoglycemic blood glucose levels that pose a real danger to the life and quality of life of many diabetics. Diabetes has reached epidemic proportions and the cost of diabetes care in the United States has been estimated at $132 billion by the American Diabetes Association. The federally funded Diabetes Control and Complications Trial proved that tighter glucose control can reduce the costly and debilitating complications associated with Diabetes. Thus, I fully support the FCC allowing the use of periodic, scheduled transmissions for DexCom's STS device.

Please feel free to contact me if I can provide any additional information with regard to this matter.

Sincerely yours,

Lois Jovanovic, MD

Lois Jovanovic, MD
Director and Chief Scientific Officer
Sansum Diabetes Research Institute
Adjunct Professor of Biomolecular Science and Engineering
University of California-Santa Barbara
Clinical Professor of Medicine
University of Southern California-Los Angeles

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SCHOOL OF MEDICINE

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3350 LA JOLLA VILLAGE DRIVE
SAN DIEGO, CALIFORNIA 92161

May 3, 2005

Ms. Marlene H. Dortch
Secretary
Federal Communications Commission
445 12th Street, S.W.
Washington, D.C. 20554

Re: DexCom Short Term Sensor (STS) Continuous Glucose Monitor Support for FCC Authorization

Dear Ms. Dortch:

I am writing in support of the Federal Communication Commission's ("FCC") authorization of the use of DexCom's Short Term Sensor Continuous Glucose Monitor ("STS"). I respectfully urge the Commission to do whatever is necessary to allow DexCom to market and sell its STS device, which is needed to provide diabetics with a unique and meaningful method of monitoring and maintaining level blood glucose levels.

I am a practicing endocrinologist who specializes in diabetes. I am also a professor of medicine at UCSD and involved in clinical research, teaching outpatient care.. As such, I am involved on a daily basis with addressing the needs of patients monitoring their blood glucose levels and I have a large number of type 1 and insulin requiring type 2 diabetics. In this way, I have become familiar with the new DexCom STS device.

DexCom needs the Commission's authority to allow the STS device to operate on the Medical Implant Communications Service ("MICS") frequency using periodic transmissions. The STS device is designed to transmit information regarding a patient's blood glucose level to a hand-held receiver on a regular schedule. Such transmissions are necessary to allow patients to receive sufficient information regarding their blood glucose levels to monitor and react to those levels properly. Unfortunately, most patients currently do not have access to methods to monitor blood glucose levels regularly throughout the day, which would allow them to adjust their diet, insulin or medication(s) to maintain a proper blood glucose level.

The provision of regularly scheduled blood glucose measurements and data are key to protecting the patients from adverse hyper- or hypoglycemic blood glucose levels that pose a real danger to the life and quality of life of many diabetics. Diabetes has reached epidemic proportions and the cost of diabetes care in the United States has been estimated at $132 billion by the American Diabetes Association. The federally funded Diabetes Control and Complications Trial proved that tighter glucose control can reduce the costly and debilitating complications associated with Diabetes. Thus, I fully support the FCC allowing the use of periodic, scheduled transmissions for DexCom's STS device.

Please feel free to contact me if I can provide any additional information with regard to this matter.

Sincerely yours,

Steve Edelman, M.D.
Professor of Medicine
Division of Endocrinology, Diabetes & Metabolism
University of California San Diego
Veterans Affairs Medical Center

Diabetes & Glandular Disease Clinic, P.A.

SHERWYN L. SCHWARTZ, M.D.
DIPLOMATE
American Board of Internal Medicine
American Board of Endocrinology

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JEROME S. FISCHER, M.D.
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JACOB VADAKEKALAM, M.D.
DIPLOMATE
American Board of Internal Medicine
American Board of Endocrinology

MARK S. KIPNES, M.D.
DIPLOMATE
American Board of Internal Medicine
American Board of Endocrinology

MARK M. DANNEY, M.D.
DIPLOMATE
American Board of Pediatrics
American Board of Pediatric Endocrinology

W. FERNANDO TRIGOSO, M.D.
DIPLOMATE
American Board of Internal Medicine
American Board of Endocrinology

MICHELLE D. WELCH, M.D.
DIPLOMATE
American Board of Internal Medicine
American Board of Endocrinology

May 6, 2005

Ms. Marlene H. Dortch
Secretary
Federal Communications Commission
445 12th Street, S.W.
Washington, D.C. 20554

Re: DexCom Short Term Sensor (STS) *Continuous* Glucose Monitor Support for FCC Authorization

Dear Ms. Dortch:

I am writing in support of the Federal Communication Commission's ("FCC") authorization of the use of DexCom's Short Term Sensor Continuous Glucose Monitor ("STS"). I respectfully urge the Commission to do whatever is necessary to allow DexCom to market and sell its STS device, which is needed to provide diabetics with a unique and meaningful method of monitoring and maintaining level blood glucose levels.

I am a practicing board-certified endocrinologist who specializes in diabetes, endocrinology and metabolism. I am also the founder and medical director of the Diabetes & Glandular Disease Clinic (established in 1979), an eight physician (all board certified endocrinologists) six extender clinical practice with over 60,000 active patients and a research unit specializing in endocrinology which employs over 200 people and has conducted over 700 Phase I through III clinical trials. I hold the following Professional Appointments:

National Advisor for Diabetes to Merck- Medco, 1995 to present
LULAC (League of United Latin American Citizens) National Medical Advisor for Diabetes
Director, Diabetes Center of Excellence, Methodist Specialty & Transplant Hospital (formerly San Antonio Community Hospital), San Antonio, Texas, 1983 – present
Director, Diabetes & Glandular Disease Research Associates, San Antonio, Texas, 1983 – present.
Director, Diabetes & Glandular Disease Clinic, San Antonio, Texas, 1979 – present

I hold or have held the following Academic Appointments:

Clinical Professor – Medicine/General Medicine. The University of Texas Health Science Center at San Antonio. From September 1, 2001 through August 31, 2003.
Reviewer for *Diabetes Care*. 1995 to present.
Endocrinology Consultant, Brook Army Medical Center, Fort Sam Houston, Texas, 1979 - 1985
Assistant Professor of Endocrinology, University of Texas Health Science Center, San Antonio,

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Texas, 1979 - 1981
Instructor, St. Luke's Presbyterian Hospital, Chicago, Illinois, 1976 – 1977

I am involved in the following Professional Activities:

Keryx Biopharmaceuticals, Overt and Micro Trials - Executive Committee/Recruitment Committee
Takeda Pharmaceuticals America, Inc. Actos™ Speakers Bureau, current
Bayer Consultants Advisory Board, current
Purdue Pharma Consultant Advisory Board, current
Lilly Device Consultants Advisory Board, current
Pharmacia & Upjohn Advisory Board, current
Merck-Medco Advisory Board, current
Parke-Davis Troglitazone Advisory Board, past
Diabetes Forecast Editorial Advisory Board, current
Quality Outcomes In Diabetes Editorial Advisory Board, current
Member, Glipizide Symposium, Roerig- Pfizer, 1983 - 1986
Advisory Committee, Upjohn Company, 1984
Humulin Advisory Committee, Eli Lilly & Company, 1984
American College of Physicians, current
American Diabetes Foundation, San Antonio Chapter, Medical Advisory Board, current
Juvenile Diabetes Foundation, San Antonio Chapter, Medical Advisory Board, current
San Antonio Endocrinology Club, current
San Antonio Internists Club, current
American Diabetes Association, current
Texas Diabetes Association, current
The Endocrine Society (former President), current
Bexar County Medical Society, current

I hold the position of Staff Physician in the following institutions:

1999 – Present	CHRISTUS Santa Rosa Medical Center 2827 Babcock Road San Antonio, Texas 78229
1979 – present	Methodist Specialty and Transplant Hospital (Formerly San Antonio Community Hospital) 8026 Floyd Curl Drive San Antonio, Texas 78229
1979 – present	Southwest Texas Methodist Hospital 7700 Floyd Curl Drive San Antonio, Texas 78229
1979 – present	St. Luke's Baptist Hospital 7930 Floyd Curl Drive San Antonio, Texas 78229

1979 – present	Methodist Children's Hospital (Formerly Methodist Women's & Children's Hospital) 7700 Floyd Curl Drive San Antonio, Texas 78229
1977 to 1979	Assistant Chief of Endocrinology BAMC Fort Sam Houston, Texas 78234

I have also authored or co-authored over 100 scientific abstracts regarding diabetes, diabetes treatment, diabetes research and diabetes device testing.

As such, I am involved on a daily basis with addressing the needs of patients monitoring their blood glucose levels. In my clinical practice I see over 500 patients per month in the office and hospital and am Principal Investigator on numerous Phase I – III clinical trials for diabetic states In this way, I have become familiar with the new DexCom STS device.

DexCom needs the Commission's authority to allow the STS device to operate on the Medical Implant Communications Service ("MICS") frequency using periodic transmissions. The STS device is designed to transmit information regarding a patient's blood glucose level to a hand-held receiver on a regular schedule. Such transmissions are necessary to allow patients to receive sufficient information regarding their blood glucose levels to monitor and react to those levels properly. Unfortunately, most patients currently do not have access to methods to monitor blood glucose levels regularly throughout the day, which would allow them to adjust their diet, insulin or medication(s) to maintain a proper blood glucose level.

The provision of regularly scheduled blood glucose measurements and data are key to protecting the patients from adverse hyper- or hypoglycemic blood glucose levels that pose a real danger to the life and quality of life of many diabetics. Diabetes has reached epidemic proportions and the costs of diabetes care in the United States has been estimated at $132 billion by the American Diabetes Association. The federally funded Diabetes Control and Complications Trial proved that tighter glucose control can reduce the costly and debilitating complications associated with Diabetes. Thus, I fully support the FCC allowing the use of periodic, scheduled transmissions for DexCom's STS device.